



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Central Region d1979b

Telephone (973) 526-6009

Food and Drug Administration
Waterview Corporate Center
10 Waterview Blvd., 3rd Floor
Parsippany, NJ 07054

August 10, 1998

WARNING LETTER

Scott Korman, President
Welsh Farms Ice Cream
55 Fairview Avenue
Long Valley, New Jersey 07853

File No.: 98-NWJ-35

Dear Mr. Korman:

During July 7-17, 1998 an Investigator from this office conducted an inspection of your manufacturing plants located at 55 Fairview Avenue, Long Valley, NJ and 780 Passaic Avenue, West Caldwell, NJ. A Form FDA 483, List of Inspectional Observations was presented to you at the conclusion of this inspection, documenting serious deviations from Title 21 of the Code of Federal Regulations (CFR), Part 110, Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food (cGMPs), especially in regard to the production of Welsh Farms Brand "Coffee Supreme" Ice Cream code 13398, causing it to adulterated within the meaning of Section 402 (a)(1) of the Federal Food, Drug and Cosmetic Act (the Act), in that:

1. Your firm failed to take adequate precautions to protect this product from being contaminated with potential allergens. For example, production records indicate that on May 13, 1998, Coffee Supreme Ice Cream was manufactured immediately following a batch of Peanut Butter Twirl Ice Cream, without prior cleaning of the processing equipment.
2. Personnel responsible for scheduling product batching were unaware of the potential contamination of products with known allergens. In fact, your firm first became aware of this situation only after several complaints of allergic reactions were received and then initiated a store-wide recall on June 15, 1998.
3. There is no documented program in effect to train employees regarding the proper handling of food products containing known allergens.

The above list is not intended to be all-inclusive of deficiencies concerning your manufacturing practices. It is your responsibility to assure that products manufactured by your firm are in compliance with all requirements of cGMPs for food products. You should take prompt action to correct these deviations and institute effective measures to prevent reoccurrence. Failure to promptly correct these deviations may result in regulatory action being initiated by the agency without further notice. These actions may include seizure and/or injunction.

REV

**Welsh Farms Ice Cream
West Caldwell, NJ**

**Warning Letter 98-NWJ-35
August 10, 1998**

The unintentional addition of allergenic substances is a serious GMP violation for which your firm has had a prior history of recalls. In 1996 and 1997 your firm initiated Class I recalls for products due to undeclared eggs, peanut oil and almonds in raw materials purchased from suppliers, these substances are known to cause serious allergic reactions in sensitive individuals. Your corrective actions should consider all potential sources of allergens to prevent similar incidents in the future.

We have received your proposed corrective actions provided to the Investigator prior to the close of the inspection. The steps outlined your memorandum dated July 16, 1998 appear to responsive to our concerns, however without supporting documentation we cannot comment on the adequacy of these measures. In response to this correspondence, we request you submit a copy of your new procedures for handling products containing known allergens and documentation of training for supervisory and production personnel concerning these procedures.

Please notify this office in writing within 15 working days of receipt of this letter, of any additional steps that your firm has implemented to correct the above violations, including the requested procedures and training records. If corrective action cannot be completed within 15 working days, state the reason for the delay and the timeframe within which the corrective measure will be implemented.

Your response should be sent to the New Jersey District Office, FDA, 10 Waterview Blvd., 3rd Floor, Parsippany, NJ 07054, Attn: Mercedes B. Mota, Compliance Officer.

Sincerely,



DOUGLAS ELLSWORTH
District Director
New Jersey District

CERTIFIED MAIL -
RETURN RECEIPT REQUESTED